



International Federation of Associations
of Pharmaceutical Physicians

————— *founded 1975* —————

THE TENTH IFAPP EUROPEAN CONFERENCE

London, Friday, 30 January 2009

Quality Issues in Clinical Research

*in collaboration with the
British Association of Pharmaceutical Physicians (BrAPP)
and with the
British Association of Research Quality Assurance (BARQA)*

Marriott Hotel West India Quay – Canary Wharf
22, Hertsmere Road • E14 4ED London, United Kingdom
Phone +44 (0)20 70931000 • Fax +44 (0)20 70931001

• IFAPP Secretariat

Kuipersweg 2T	•	Phone +31 (0)348 489305	•	e-mail: ifapp@planet.nl
3449 JA Woerden	•	Fax +31 (0)348 489301	•	website: www.ifapp.org

• CPD Credits

This conference has been awarded with 6.75 CPD credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom

• Scientific Committee

Dr Jane Barrett • Dr Luis F. Colliá • Dr Domenico Criscuolo • Prof Dr Gerfried Nell

• Programme

08h 15 - 08h 45	• Registration		
08h 45 - 09h 00	Introductory Remarks	<i>Domenico Criscuolo</i>	<i>IFAPP</i>
<p>• Morning Session Looking for a Quality System</p>			
<p><i>Chairs: Fergus Sweeney (EMEA) and Domenico Criscuolo (IFAPP)</i></p>			
09h 00	GCP Inspections: Role of EMEA	<i>Fergus Sweeney</i>	<i>EMEA</i>
09h 30	Role and Activities of Italian Inspectorate	<i>Umberto Filibeck</i>	<i>AIFA</i>
10h 00	Safety Issues during Health Authorities Inspections	<i>Jane Winter</i>	<i>BrAPP</i>
10h 30	• Coffee		
11h 00	The Role of Audits in the Quality Process	<i>Anna Piccolboni</i>	<i>Zambon Group</i>
11h 30	Are Auditors Properly Trained?	<i>David Butler</i>	<i>BARQA</i>
12h 00	Discussion		
12h 30	• Lunch		
<p>• Afternoon Session EU and Quality</p>			
<p><i>Chairs: Jane Barrett (BrAPP) and Matt Jones (BARQA)</i></p>			
13h 30	EU Focus on Quality	<i>Vincent Yeung</i>	<i>MHRA</i>
14h 00	Experiences in Regulatory Inspections	<i>Matt Jones</i>	<i>BARQA</i>
14h 30	The Experience of Roche QA	<i>Beat Widler</i>	<i>Roche</i>
15h 00	Quality and CRO: an Example	<i>Angela Del Vecchio</i>	<i>AIFA</i>
15h 30	Computerized Systems Validation: a Risk-Based Approach	<i>Chris Montgomery</i>	<i>BARQA</i>
16h 00	Discussion		
16h 30	Concluding Remarks and End of Meeting	<i>Matt Jones</i> <i>Jane Barrett</i>	<i>BARQA</i> <i>BrAPP</i>

• Contents of the Conference

The 2009 Conference will cover a very relevant topic: how to ensure and how to control Quality of Clinical Research. IFAPP Scientific Committee believes that this issue needs a full day debate, with contributions from all players in clinical development, and from speakers representing EMEA, Industry and Scientific Associations. And it is easy to anticipate that this Conference will be very fruitful for all interested parties.

• Target Audience

The conference is addressed to pharmaceutical physicians and quality assurance managers: in addition all professionals involved in clinical research and regulatory affairs as well as regulators and clinical investigators, and all those involved in the development of medicinal products, will benefit from this up-to-date review of quality issues.

• Language

The conference language is English.

• Conference Venue

The conference will take place at:

Marriott Hotel West India Quay
22, Hertsmere Road
E14 4ED London
Phone +44 (0)20 70931000
Fax +44 (0)20 70931001

For your information please note that London City is the closest airport. If you want IFAPP to reserve your hotel accommodation, please complete the enclosed hotel reservation form and return it to the IFAPP secretariat as soon as possible. We reserve a number of rooms for attendees until 1 December 2008.

• Hotel Accommodation

On the enclosed hotel reservation form you will find information about several hotels. If you want us to reserve your hotel accommodation, please mention your hotel preference.

• Certificate of Attendance

The IFAPP will grant a Certificate of Attendance to all delegates. The conference is awarded with CPD credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom.

• Registration Fee

You can register for this conference by filling in the enclosed registration form and returning it to the IFAPP secretariat. Registrations will be accepted only upon receipt of payment.

The registration fee is **EUR 800.00**
BrAPP and BARQA members **EUR 700.00**

You should pay the registration fee by bank transfer to:

Account no. 55.84.60.739
ABN AMRO BANK
P.O. Box 2007
3440 DA WOERDEN
The Netherlands

BIC: ABNANL2A
IBAN: NL30ABNA0558460739

• Lunches and Coffee Breaks

Coffee and lunch are included in the registration fee.

• Confirmation

After receipt of your registration form you will receive a confirmation and an invoice.

• Cancellation

In the event of cancellation on or before **1 December 2008** the fee will be reimbursed by deduction of a 20% (EUR 160.00 or respectively EUR 140.00) administration fee.

In case of cancellation after 1 December 2008 there will be no reimbursement on the registration fee.

Replacement of a delegate can occur at any time without additional charge.

• Further Information

For further information please contact:

IFAPP Secretariat

Kuipersweg 2T
3449 JA WOERDEN
The Netherlands

Phone: +31 (0)348 489305
Fax: +31 (0)348 489301

E-mail ifapp@planet.nl
Website www.ifapp.org